REMARKS

Favorable reconsideration and allowance are respectfully requested. Claims 1-4, 6-19, 21-23, 25-31 and 33-47 are pending, and claims 8, 9, 21-23, 30, 33, 34 and 41-47 are withdrawn from consideration (and claims 30 and 41-47 are withdrawn because they are directed to a non-elected species). By this amendment, claims 1-4 have been cancelled, without prejudice, and claims 6-7, 25-31 and 35-47 have been amended to correct certain informalities in the claims and to correct the dependency of the currently pending claims. These amendments do not introduce new matter. Therefore, claims 6-7, 25-31, and 35-40 remain pending and at issue.

Objection to the Disclosure

The disclosure was objected to because it contained embedded hyperlinks and/or other forms of browser-executable code. Applicants have amended the specification to delete the references to hyperlinks. Reconsideration of the objection to the specification is requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 6 and 7 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner alleged that the specification does not provide evidence for a therapeutically effective use of the A34 immunoglobulin and contends that the specification does not provide actual evidence that the therapeutic uses disclosed in the specification were successfully carried out (Official Action at 4). Therefore, the Examiner alleged that the quantity of experimentation necessary, the amount of guidance needed, and the unpredictability of whether or not the intended use would be effective would require undue experimentation.

Applicants respectfully traverse. The specification describes how the A34 protein can be isolated and characterized (p 25-28) and how antibodies to the A34 protein can be generated (page 28 et seq.). The antibodies and fragments thereof are characterized in detail (pages 28-30) and Tables 3-5 provide information concerning immunohistochemical analyses performed on gastric/stomach cancer cells, ovarian cancer cells, and esophageal carcinoma cells with A34 clone 342. Table 6 provides the immunohistochemical analyses of A34 protein expression in normal tissues as detected by the A34 antibody clone 342. Example 8 discloses the utilities of antibodies to A34 alone or in combination with supplemental therapeutics. Example 9 discloses the use of antibodies of the invention as targeting agents in conjunction with other cancer therapies and Example 12 discloses the use of antibodies of the invention in a composition or treatment regimen. Therefore, the specification provides ample guidance concerning how to make and use the claimed compositions, especially when the disclosure is considered by a person of ordinary skill in the art.

The specification need not contain a working example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). In view of the foregoing discussion concerning the ample guidance in the specification, Applicants submit that one skilled in the art will readily understand how to reduce the claimed invention to practice without undue experimentation.

In order to make an enablement rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A disclosure that contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in

describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

Applicants respectfully submit that the Examiner has not met that burden. The Examiner simply concluded that the enablement requirement has not been satisfied because the specification does not provide "actual evidence" that the compositions were successfully used. That is not the standard. There is nothing in the caselaw or the patent office rules that supports the proposition that a patent application must provide clinical evidence that a claimed composition was successfully used in order to provide an enabling disclosure. The present specification provides sufficient information for one of skill in the art to make and use the claimed invention in the absence of undue experimentation. As stated in *Marzocchi*, it is incumbent upon the Patent Office to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. The Examiner has not established a reasonable basis to question the enablement provided for the presently claimed invention, and thus the instant enablement rejection is untenable and should be withdrawn.

Favorable reconsideration and withdrawal of the enablement rejection are respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-4, 6-7, 25-31 and 35-47 were rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over Jacobs et al. (WO 99/26972; "Jacobs"). The Examiner asserted that the sequence of A34 disclosed in Jacobs is the same as SEQ ID NO: 1

of the instant invention and therefore, an antibody directed to that antigen would meet the claimed limitations.

Without conceding the propriety of the rejection, Applicants have canceled claims 1-4, without prejudice. While Jacobs discloses the existence of the A34 protein and generally that antibodies may be made to that protein, there is no disclosure of a specific antibody to A34 in Jacobs. In contrast, the instant claims relate to discrete antibody sequences which are not disclosed in Jacobs. To anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984). Therefore, Jacobs cannot anticipate the instant claims. Favorable reconsideration and withdrawal of the anticipation rejection are respectfully requested.

CONCLUSION

In view of the foregoing remarks and amendments, favorable consideration and allowance of all pending claims is respectfully requested.

Respectfully submitted,

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